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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,739	ROBERTSON ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4 and 52-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4 and 52-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 2-4 and 52-66 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 10 December 1998. It is noted, however, that applicant has not filed a certified copy of the GB9827228.9 application as required by 35 U.S.C. 119(b).

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows: The Oath and Declaration filed on 6/8/1002 indicates that this application is filed under 35 U.S.C. § 120 or 35 U.S.C. § 365 (c) of PCT/GB99/04182 filed on 12/10/1999. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after

November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claims 1, 3, 4, 52, 53, 54, 62-66 under 35 U.S.C. 102(b) as being anticipated by Rao et al., (1988, IDS #1 filed on 05/19/2005, Am J obstet Gynecol, July 1998, vol. 159, pages 94-98) are withdrawn because the amended claims are not anticipated by Rao et al., of record.

The Following Are New Ground of Rejection

Claim Rejections - 35 USC § 103

Claims 2-4, 52-58, 61, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrakou et al., International Journal of Oncology, 1997, vol. 11, suppl., page 902, IDS filed on 02/10/2006 #12.

Claims 2-4, 52-58, 61, 62, and 66 are drawn to method of detecting a modified form of a wild-type cancer-associated protein marker (or breast cancer associated marker in claims 55 and 66, or MUC1 in claim 56) in a bodily fluid from humans having

various stages of cancer from substantially asymptomatic to one has prior treatment) using autoantibodies obtained from the human.

Petrakou et al., teach that the circulating autoantibodies present in advanced breast cancer patient have the highest reactivity for tumor associated MUC1 (see 2nd paragraph) based on an in vitro method, wherein detection of the complexes between the antibodies and three different MUC1. The "tumor associated MUC1 antigen" of the prior art is same as the limitation "a modified form of a wild-type protein" in the instant claims. In other words, Petrakou et al., teach that tumor associated MUC1 antigen preferentially reactive to human autoantibodies from breast cancer patients. Petrakou et al., teach MUC1 is involved in malignant transformation, and being shed into a bodily fluid.

With regards to biological sample from various mammals with different stages of cancer, Petrakou et al., teach that obtaining bodily fluid sample from mammal or human for that matter is well within the level of ordinary skill in the art.

Since Petrakou et al., teach that the circulating autoantibodies present in advanced breast cancer patient detect the modified form of the wild-type MUC1, i.e. tumor associated MUC1, it would have been obvious to one of skill in the art to use autoantibodies from human breast cancer patients to detect tumor associated MUC1 antigen, i.e. a modified form of wild-type antigen with a reasonable expectation of success since antigen-antibody complexes assay had been well known in the art before the effective filing date of the instant application. It would have been well within the level of ordinary skill in the art to tinker with the procedures of Petrakou et al., by using

biological sample containing the antigen and the autoantibodies as the reagent to arrive at the optimum process and better control. See In re Kronig, 190 USPQ 425.

One of ordinary skill in the art would have been motivated to use autoantibodies from human because the antibody is superior to detect the tumor associated antigen i.e. "preferentially reactive with tumor associated MUC1 antigen" as taught by Petrakou et al.

Claims 59, 60, and 63-65 rejected under 35 U.S.C. 103(a) as being unpatentable over Petrakou et al., as applied to claims 2-4, 52-58, 61, 62, and 66 above, and further in view of of Petrarca et al., European Journal of Cancer, vol. 32A, pages 2155-2163, 1996, #7 of IDS filed on 02/10/2006.

Claims 59, 60, and 63-65, not rejected above are drawn to method involving autoantibodies (immobilized on a solid surface in claim 63, and other- art known method) obtainable from mononucleocyte isolated from a patient.

As stated above, Petrakou et al., teach that autoantibodies from breast cancer patient reacts preferentially to a tumor associated antigen, thus demonstrate that existence of autoantibodies preferentially reactive to a modified form of the wild-type MUC1 antigen.

Petrakou et al., do not teach the technical details of making autoantibodies obtainable from mononucleocyte isolated from a patient with breast cancer, or advanced breast cancer, or immobilizing antibody to a solid surface.

However, Petrarca et al., teach at page 2156, left column, 2nd paragraph under the subheading *Cell cultures*, teach that making autoantibodies obtainable from mononucleocyte isolated from a patient with breast cancer, or advanced breast cancer had been well known before the effective and Petrarca et al., teach at page 2156 under the heading *ELISA* that immobilizing antibody to a solid support or detection label had been well known in the art at the time the instant application was filed.

Therefore, it would have been obvious to one of skill in the art to use autoantibodies from human breast cancer patients to detect tumor associated MUC1 antigen, i.e. a modified form of wild-type antigen with a reasonable expectation of success since antigen-antibody complexes assay with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to use known autoantibodies and known techniques to save time.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 2/10/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642